

Agricultural Bioterrorism Protection Act of 2002: Implementation of Agricultural Select Agents

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Public Health Security & Bioterrorism Preparedness and Response Act, 2002



Senator Daschle Received
Anthrax Tainted Letter
on October 9, 2001



Announced June 6, 2002
by President Bush

P.L. 107-188 Signed by President Bush, June 12, 2002

Public Health Security and Bioterrorism Preparedness Response Act of 2002

- ❖ Purpose: To improve the ability of the US to prevent, prepare for, and respond to bioterrorism and other public health emergencies
- ❖ Subtitle B cited as the “Agricultural Bioterrorism Protection Act of 2002” expanded USDA authority
- ❖ Requirements
 - ❑ List of biological agents and toxins
 - ❑ Notification of Possession
 - ❑ Registration for Possession, Use, and Transfer
 - ❑ Exemptions

Promulgated Regulations: Mandated Partnerships....

- APHIS promulgated new regulations – expanded authority for intrastate movement (9 CFR Part 121 & 7 CFR Part 331)
- CDC promulgated new regulations (42 CFR Part 73)
- Department of Justice/Federal Bureau of Investigations (DOJ/FBI) implemented security risk assessments (SRA) on all entities and individuals



....and Timeline for Implementing Agricultural Select Agent Rule

➤ June 12, 2002	➤ Review Statutory requirements
➤ August 11, 2002	➤ Promulgate Ag. Select Agent list & notification requirements
➤ October 10, 2002	➤ Receive notification of Possession
➤ December 9, 2002	➤ Final interim rules ➤ MOU signed by USDA & HHS Secretaries
➤ February 14, 2002	➤ Final interim rule effective
➤ November 12, 2003	➤ Full compliance by current possessors
➤ Fall, 2004	➤ Single Registration Program promulgated by USDA & HHS

Phase In for Current Possessors of Select Agents

- February 11, 2003 effective date for regulations
- March 12, 2003 Registration applications submitted. Responsible Officials (RO) submit background materials to the DOJ/FBI
- June 12, 2003 security plans submitted
- September 12, 2003 security plans implemented
- November 12, 2003 full compliance upon application

Select Agent Program: Meeting Deadlines

- Promulgated Interim Final Rules on November 3, 2003 – ensure all entities currently possessing and conducting research would not be disrupted on November 12, 2003
- By November 12, 2003 APHIS Issued Provisional Certificates of Registration for 75 entities
- Issued Denial letters for two entities due to safety concerns
- APHIS determined 17 entities were exempt from the regulations and another 17 entities withdrew their applications.

Entity Registration Depended on Designating Responsible Official

- Entity must designate a Responsible official (RO)
 - - Must have the authority and control to ensure compliance with the regulations
- An alternate RO may also be designated
- RO submits personal information to APHIS

Responsible Official Role Extensive and Legally Binding

- RO submits required information to the DOJ/FBI for the security risk assessment (SRA)
 - RO security risk assessment tied to the entity
 - Individual SRA contingent on legitimate need for access & training
- RO submits entity and select agent information to APHIS (fondly known as the 4B)
- RO in charge of submitting the safety and security plans
- Civil penalty up to \$250,000 for an individual and up to \$500,000 for an entity
- Transfer of a select agent to an unregistered entity or person possible civil penalty (above) and/or imprisonment for up to 5 years

Next Steps for Select Agent Program

- ✓ APHIS/CDC set up working group to address all aspects of coordinating the select agent program.
 - Concurrence on overlap registration
 - Streamline registration process through defining "Lead Agency"
 - Outreach to regulated entities
- ✓ APHIS/CDC and the DOJ/FBI will ensure the SRA process is seamless.
- ✓ Review and republish lists of select agents toxins biennially or more often as needed.

How To Contact the Agencies Responsible for the Select Agent Program

- **USDA/APHIS**

www.aphis.usda.gov/lpa/issues/bioterrorism

- **HHS/CDC**

www.cdc.gov

- **DOJ/FBI**

www.fbi.gov/terrorinfo/bioterrorfd961.htm